

Practitioner's Docket No. U 016181-4

Optional Customer No. Bar Code



00140

PATENT TRADEMARK OFFICE

CHAPTER II

**TRANSMITTAL LETTER  
TO THE UNITED STATES ELECTED OFFICE (EO/US)  
(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)**

|  |  |                       |
|--|--|-----------------------|
| INTERNATIONAL APPLICATION NO.<br>PCT/IN2003/000333   | INTERNATIONAL FILING DATE<br>14 OCTOBER 2003 | PRIORITY DATE CLAIMED |
| TITLE OF INVENTION<br>A METHOD FOR THE MANUFACTURE OF LOVASTATIN   |  |                       |
| APPLICANT(S)<br>1. VAISHNAV, Sanjay Kumar<br>2. THAKUR, Bhupendra Harishchandra<br>3. KADAM, Subhash Rajaram |  |                       |

**Mail Stop PCT  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450**

**ATTENTION: EO/US**

**COMMUNICATION**

In response to the requirement in the Official Communication of

**CERTIFICATION UNDER 37 C.F.R. 1.8(a) and 1.10\***

*(When using Express Mail, the Express Mail label number is **mandatory**;  
Express Mail certification is optional.)*

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.  
**37 C.F.R. 1.8(a)**

☐ with sufficient postage as first class mail.

**37 C.F.R. 1.10\***

☒ as "Express Mail Post Office to Addressee"  
Mailing Label **EV 815 587 377US**  
(mandatory)

**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office.

*Geraldine Marti*  
Signature

Date: December 20, 2006

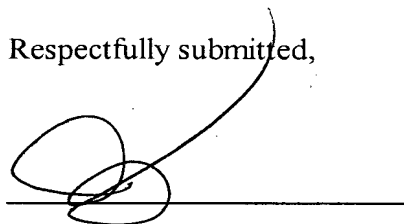
Geraldine Marti  
(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).  
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

October 16, 2006, for a Sequence Listing Applicants respectfully note that the application does not contain an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides as would be required to trigger the Sequence Listing requirements of 37 CFR 1.821 *et seq.*

Accordingly, Applicants respectfully submit that the requirement for a Sequence Listing should be withdrawn.

Respectfully submitted,

A handwritten signature in black ink, consisting of a large loop and a trailing line, positioned above a horizontal line.

JANET I. CORD  
LADAS & PARRY LLP  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, NEW YORK 10023  
REG.NO.33,778(212)708-1935

Practitioner's Docket No. U 016181-4

Optional Customer No. Bar Code



00140

PATENT TRADEMARK OFFICE

CHAPTER II

**TRANSMITTAL LETTER  
TO THE UNITED STATES ELECTED OFFICE (EO/US)  
(ENTRY INTO U.S. NATIONAL PHASE UNDER CHAPTER II)**

| INTERNATIONAL APPLICATION NO. | INTERNATIONAL FILING DATE | PRIORITY DATE CLAIMED |
|-------------------------------|---------------------------|-----------------------|
| PCT/IN2003/000333             | 14 OCTOBER 2003           |                       |

TITLE OF INVENTION

A METHOD FOR THE MANUFACTURE OF LOVASTATIN

APPLICANT(S)

1. VAISHNAV, Sanjay Kumar
2. THAKUR, Bhupendra Harishchandra
3. KADAM, Subhash Rajaram

Mail Stop PCT  
Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

ATTENTION: EO/US

**COMPLETION OF FILING REQUIREMENTS  
FOR INTERNATIONAL APPLICATION ENTERING U.S. NATIONAL STAGE  
IN U.S. ELECTED OFFICE (EO/US) UNDER 35 U.S.C. § 371**

*(check and complete the applicable item, if applicable)*

- ☒ This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. § 1.495 (FORM PCT/DO/EO/905).
- ☒ A copy of FORM PCT/DO/EO/905 accompanies this response.

**CERTIFICATION UNDER 37 C.F.R. 1.10\***

*(Express Mail label number is mandatory.)*

*(Express Mail certification is optional.)*

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith are being deposited with the United States Postal Service on this date **December 20, 2006**, in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number **EV 815 587 377 US**, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

Geraldine Marti

*(type or print name of person mailing paper)*

Signature of person mailing paper

**WARNING:** Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Completion of Filing Requirements for International Application Entering U.S. Elected Office (EO/US)

page 1 of 7) 13-19

**WARNING:** Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 C.F.R. § 108(2)(xi).

**NOTE:** Documents and fees must be clearly identified as a submission to enter the national stage under 35 U.S.C. § 371. Otherwise, the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.495(g).

## DECLARATION OR OATH

**NOTE:** 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17 (iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the . . . oath or declaration in order to prevent abandonment of the application . . . . The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of **thirty** months after the priority date."

I. (a) ☒ No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

OR

(b) ☐ The declaration or oath that was filed was determined to be defective. A new original oath or declaration is attached.

**NOTE:** For surcharge fee for filing declaration after filing date complete item IV(3)

**NOTE:** NOTE: Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:

- (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
- (B) serial number and filing date;
- (C) attorney docket number which was on the specification as filed;
- (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
- (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 602, 8<sup>th</sup> ed.

**NOTE:** Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. § 1.10(c).

**NOTE:** See 37 C.F.R. § 1.41(a).

(complete as applicable)

Attached is a

- (a) ☐ Statement by practitioner that papers attached to declaration are a copy of those filed in PTO to get a filing date
- (b) ☐ Statement that substitute specification contains no new matter.
- (c) ☐ Preliminary Amendment
- (d) ☐ Submission of "Sequence Listing," computer readable copy, and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence

**TRANSMITTAL OF ENGLISH TRANSLATION  
OF NON-ENGLISH LANGUAGE PAPERS**

- II. ☐ Submitted herewith is an English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 C.F.R. 1.495(c))

NOTE: For fee for processing a non-English application, complete item IV(4).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 C.F.R. § 1.69(b).

**FEEES**

**III.**

NOTE: See 37 C.F.R. § 1.28(a).

1. Fees for search, exam or claims

- ☐ Non-U.S. Search Report filed —\$400.00;  
small entity—\$200.00 \$ \_\_\_\_\_
- ☐ No Search Report —\$500.00; small entity —\$250.00 \$ \_\_\_\_\_
- ☐ Exam Fee not paid to U. S—\$200.00; small entity—\$100.00 \$ \_\_\_\_\_
- ☐ Search and Exam fee with U.S. WO or IPER conditions  
not satisfied—\$100.00; small entity—\$50.00 \$ \_\_\_\_\_
- ☐ Search and Exam fee with U.S. WO or IPER conditions  
satisfied—\$0.00 \$ \_\_\_\_\_

- ☐ Spec and drawing, each 50 pages over 100  
37 C.F.R. 1.16(s)—\$250.00 \$ \_\_\_\_\_
- ☐ Each independent claim in excess of 3  
(37 C.F.R. § 1.492—\$200.00; small entity—\$100.00) \$ \_\_\_\_\_
- ☐ each claim in excess of 20  
(37 C.F.R. § 1.492—\$50.00; small entity—\$25.00) \$ \_\_\_\_\_
- ☐ multiple dependent claims(s)  
(37 C.F.R. § 1.492—\$360.00; small entity—\$180.00) \$ \_\_\_\_\_

2. Surcharge fees

- ☒ surcharge set forth in 37 C.F.R. § 1.492(e) for accepting  
the declaration later than 30 months after the priority date  
in filing an application in the U.S. as a designated  
office—\$130.00; small entity—\$65.00 **\$130.00** \_\_\_\_\_

*NOTE: The processing fee in the next item 3 below is not subject to a reduction for small entity status.*

3. ☐ processing fee set forth in 37 C.F.R. § 1.492(f)  
for acceptance of an English translation later  
than 30 months after the priority date—\$130.00 \$ \_\_\_\_\_

**Total Fees** **\$130.00** \_\_\_\_\_

**SMALL ENTITY STATUS**

- IV. a. ☐ A Statement or Written Assertion that this filing is by a small entity

*NOTE: See 37 C.F.R. § 1.28(a).*

*(check and complete applicable items)*

- ☐ is attached.  
☐ was filed on \_\_\_\_\_.  
☐ was made by paying the basic national fee as a small entity.

- b. ☐ A separate refund request accompanies this paper.

12/26/2006 GFREY1 00000053 10571192

01 FC:1617

130.00 DP

## EXTENSION OF TIME

(complete (a) or (b), as applicable)

V.

The proceedings herein are for a patent application. Accordingly, the provisions of 37 C.F.R. § 1.136(a) apply.

- (a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below:

|                                     | Extension<br>(months) | Fee for other than<br>small entity | Fee for<br>small entity |
|-------------------------------------|-----------------------|------------------------------------|-------------------------|
| <input checked="" type="checkbox"/> | one month             | \$ 120.00                          | \$ 60.00                |
| <input type="checkbox"/>            | two months            | \$ 450.00                          | \$ 225.00               |
| <input type="checkbox"/>            | three months          | \$ 1,020.00                        | \$ 510.00               |
| <input type="checkbox"/>            | four months           | \$ 1,590.00                        | \$ 795.00               |

**NOTE:** The 2-month time period for reply to A Notice to File Missing Parts of an Application is not identified on the Notice as a statutory period subject to 35 U.S.C. 133. Thus, extensions of time of up to 5 months under 37 CFR 1.136(a), followed by additional time under 37 CFR 1.136(b), when appropriate, are permitted. MPEP 710.02(d)(e), 8<sup>th</sup> ed.

☐ five months \$ 2,160.00 \$ 1,080.00

Fee: \$120.00

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for \_\_\_\_\_ months has already been secured. The fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ \_\_\_\_\_

or

- (b) ☐ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

12/26/2006 GFREY1 00000053 10571192

02 FC:1251

120.00 0P

## TOTAL FEE DUE

VI.

The total fee due is:

|                        |                        |
|------------------------|------------------------|
| Completion fee(s)      | <u>\$130.00</u>        |
| Extension fee (if any) | <u>\$120.00</u>        |
| <b>TOTAL FEE DUE</b>   | <b><u>\$250.00</u></b> |

## PAYMENT OF FEES

VII.

- ☒ Enclosed is a check in the amount of \$250.00  
☐ Charge Account No. 12-0425 in the amount of \$ \_\_\_\_\_  
☐ A duplicate of this request is attached.

*NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).*

## AUTHORIZATION TO CHARGE ADDITIONAL FEES

VIII.

**WARNING:** *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.*

**NOTE:** *"A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).*

**NOTE:** *"Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).*

- ☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 12-0425

- ☒ 37 C.F.R. § 1.492(a), (b) or (c) (search or exam fee)  
☐ 37 C.F.R. § 1.492(b), (c), and (d) (presentation of extra claims)

**NOTE:** *Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.*

- ☒ 37 C.F.R. 1.16(s) (spec and drawing, each 50 pages over 100)  
☒ 37 C.F.R. § 1.17 (application processing fees)  
☒ 37 C.F.R. § 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a)).

**NOTE:** Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application **only after the mailing of the notice of allowance**. Accordingly, general authorizations to any fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL 85-B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1.311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant and submitted, § 1.311(b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b), Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.

[X] 37 C.F.R. § 1.492(e) and/or (f) surcharge fees for filing the declaration and/or an English translation of an international application later than 30 months from the earliest-claimed priority date.

**WARNING:** It would be wise to always check this last authorization.

Refund any overpayment to deposit account 12-0425.

Reg. No.: 33,778

Tel. No.: (212)708-1935

Customer No.:00140



00140

PATENT TRADEMARK OFFICE

  
SIGNATURE OF PRACTITIONER

Janet I. Cord

(type or print name of practitioner)

P.O. Address

c/o Ladas & Parry LLP  
26 West 61<sup>st</sup> Street  
New York, N.Y. 10023



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
 United States Patent and Trademark Office  
 Address: COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 www.uspto.gov

| U.S. APPLICATION NUMBER NO. | FIRST NAMED APPLICANT | ATTY. DOCKET NO. |
|-----------------------------|-----------------------|------------------|
| 10/571,192                  | Sanjay Kumar Vaishnav | U0161814         |

INTERNATIONAL APPLICATION NO.

PCT/IN03/00333

I.A. FILING DATE

PRIORITY DATE

10/14/2003

00140

LADAS & PARRY  
 26 WEST 61ST STREET  
 NEW YORK, NY 10023

OCT 16 2006

CONFIRMATION NO. 1783

371 FORMALITIES LETTER



\*OC000000020640360\*

Date Mailed: 10/12/2006

### NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 03/09/2006
- Copy of the International Search Report filed on 03/09/2006
- Preliminary Amendments filed on 03/09/2006
- Information Disclosure Statements filed on 03/09/2006
- Request for Immediate Examination filed on 03/09/2006
- U.S. Basic National Fees filed on 03/09/2006
- Specification filed on 03/09/2006
- Claims filed on 03/09/2006
- Abstracts filed on 03/09/2006
- Drawings filed on 03/09/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$130 for a Large Entity:

- \$130 Surcharge.
- This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c) Applicant must provide an initial paper or compact disc copy of the "Sequence Listing", **as well as an amendment specifically directing its entry into the application** and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

**For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:**

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ [ebc@uspto.gov](mailto:ebc@uspto.gov)

**ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

*A copy of this notice **MUST** be returned with the response.*

BARBARA A CAMPBELL

Telephone: (703) 308-9140 EXT 217

**PART 1 - ATTORNEY/APPLICANT COPY**

| U.S. APPLICATION NUMBER NO. | INTERNATIONAL APPLICATION NO. | ATTY. DOCKET NO. |
|-----------------------------|-------------------------------|------------------|
| 10/571,192                  | PCT/IN03/00333                | U0161814         |

FOR: ACT/DO/EO/905 (371 Formalities Notice)